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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/182,645 10/30/98 LI

J 23737

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HM12/0531

EXAMINER

| | |
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| WANG, S | |
| ART UNIT | PAPER NUMBER |

1617

DATE MAILED:

05/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/182,645

Applicant(s)

LI ET AL.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25,27-33 and 35-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-25,28-31 and 35-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,32,33 and 39-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

1. The request filed on March 14, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09182645 is acceptable and a CPA has been established. An action on the CPA follows.

Applicants' election in the parent application is presumed to carry over to the instant CPA since applicants have not indicated a contrary intention.

The claims have been examined insofar as they read on the elected species.

Claim Rejection 35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 27, 32, 33 and 39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (DERWENT ACC-NO: 1997-065937), Ning (DERWENT-ACC-NO: 1997-416112) and Tanuma (AB and AC).

2. Wang teaches method of treatment of diabetes comprising administering ginseng to the patient. See the abstract. Ning teaches method of treatment of ischemia comprising administering ginseng to the patient. See the abstract. The ginseng is administered in the form of tea. See both abstracts. Tanuma teach that ginseng hot water extract containing the lignin glycoside herein. See page 5, lines 2-4, the embodiment 1 at page 5, and page 12 in JP 3-205402 the translated copy. Therefore the claimed method herein read on the method taught by Wang and Ning. Regarding the functional limitation about the detailed enzyme and biochemical function, it is

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well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art."

Claim Rejections 35 U.S.C – 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 27, 32³³~~34~~ and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanuma (AB and AC) in view of both Wielckens et al. (BQ), and Wachsmann (BO).

Tanuma (AB) teach a lignin glycoside, an inhibitor of poly(ADP-ribose)glycohydrolase, having following properties:

- i) Lignin and polysaccharide are bonded,
- ii) the molecular weight is 8000 to 10000,
- iii) the bonding ration of lignin and polysaccharide is 1:1 or 2:1,
- iv) polysaccharide is composed of 10-20 % of uronic acid and 80-90 % of neutral sugar.

See, particularly, the claims. The lignin glycoside can be obtained from pine corn, ginseng, tea, grass dogwood. See, particularly, page 4, lines 20-21 of the translated copy. The lignin glycoside comprises the structure claimed in claim 33 of instant application. See page 12 of the translated copy. Tanuma further teaches that the inhibitor is useful as anti-cancer and antiviral

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agent, useful as cytokine intensifying agent or cytokine production inducing agent, immunotherapeutic agents. See the first paragraph on page 4.

Tanuma (AC) also teach another lignin glycoside, an inhibitor of poly(ADP-ribose)glycohydrolase, having following properties:

- i) Lignin and polysaccharide are bonded,
- ii) the molecular weight is 6000 to 14000,
- iii) the bonding ration of lignin and polysaccharide is 1:1 or 2:1,
- iv) polysaccharide is composed of 30-40 % of uronic acid and 60-70 % of neutral sugar.

See, particularly, the claims. The lignin glycoside can be obtained from pine cone, tea, ginseng and grass dogwood etc. See, particularly, page 5, lines 2-4. Tanuma further teaches a process of employ the lignin glycoside for treating poly(ADP-ribose)glycohydrolase related diseases. See, particularly, page 5, lines 15-36. (translated copy).

Tanuma do not specifically teach the employment of the lignin glycoside for treating disease directly related to the activity of poly(ADP-ribose)polymerase, e.g., cellular energy depletion, apoptosis or neurological disorder.

However, Wachsman teaches that inhibitor of poly(ADP-ribose)glycohydrolase will retard apoptosis. See, particularly, page 30, left column, lines 11-13. Wachsman also teach depletion of intracellular NAD will result depletion of cellular energy. See, page 30, right column. Wielckens et al. teach that the depletion of NAD is caused by drastic stimulation of poly(ADP-ribose) turnover. The poly(ADP-ribose) turnover is due to the high activity of both poly(ADP-ribose)polymerase and poly(ADP-ribose)glycohydrolase. See, particularly, page 12876, right column.

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Therefore it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ lignin glycosides of Tanuma or the like and the process of Tanuma for treating or preventing diseases or conditions related to apoptosis or for decreasing cellular energy depletion.

A person of ordinary skill in the art would have been motivated to employ lignin glycosides of Tanuma or the like and the process of Tanuma for treating or preventing diseases or conditions related to apoptosis or for decreasing cellular energy depletion because the lignin glycoside is a known poly(ADP-ribose)glycohydrolase inhibitor, poly(ADP-ribose)glycohydrolase inhibitors are known for retarding apoptosis and high activity of poly(ADP-ribose)glycohydrolase is responsive for the high turnover of poly(ADP-ribose) and consequently responsive for NAD depletion and cellular energy depletion. Further, since poly(ADP-ribose)polymerase and poly(ADP-ribose)glycohydrolase work in concert in the process of poly(ADP-ribose) turnover, it is reasonably expected that inhibiting one enzyme will downregulate the activity of the other, i.e., inhibiting poly(ADP-ribose)glycohydrolase will downregulate the activity of poly(ADP-ribose)polymerase. Regarding the newly added claims 39-41, note that cancer is considered a disease related to cell proliferative capacity. Further, the inhibitor are known to be useful as immunotherapeutic agents.

5. Claims 27, 32-33 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (DERWENT ACC-NO: 1997-065937) or Ning (DERWENT-ACC-NO: 1997-416112) in view of Tanuma (AB and AC).

6. Wang teaches method of treatment of diabetes comprising administering ginseng to the patient. See the abstract. Ning teaches method of treatment of ischemia comprising administering

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ginseng to the patient. See the abstract. The ginseng is administered in the form of tea. See both abstracts.

7. The primary references do not teach expressly the employment of lignin glycoside for treatment of diabetes.

1. However, Tanuma teach that the particular PARG inhibitor herein, lignin glycoside, are found in ginseng. See the above discussion. Tanuma further teach that the lignin glycoside is hot water extractable. See page 6 in JP 3-205402 the translated copy. Therefore, it is prima facie obvious to use the hot water extractable part for treatment of diabetes. Regarding the functional limitation about the detailed enzyme function, it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter.

Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." The ultimate utility for the claimed substance is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Shengjun Wang

AU 1617

May 26, 2001



RUSSELL TRAVERS
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